REMARKS

Claims 1-5, 10-13, 15, 17-21, and 23-46 are pending in the application. Claims 6-9, 14, 16 and 22 are cancelled. Claims 2-4, 12-13, 15, 20-21, 24-25, 27-30, 33-38, and 44-45 are listed by the Examiner as withdrawn. Thus, Claims 1-5, 10-13, 15, 17-21, and 23-46 are presently under examination.

Election/Restriction

The Examiner's comments on election/restriction of claims are noted. Claims 6-9, 14, 16 and 22 have previously been cancelled. Claims 2-4, 12-13, 15, 20-21, 24-25, 27-30, 33-38, and 44-45 are listed as withdrawn by the Examiner but are being maintained in the case currently for the reasons described below.

The Examiner's reference to withdrawn claims 2-4, 12-13, 15, 20-21, 24-25, 27-30, 33-38, and 44-45 is noted. These claims remain pending herein, because they are entitled to rejoinder. See MPEP 821 et seq.

Moreover, with regard to claims 10, 12 and 13, it is again noted that claims 10, 12 and 13 are clearly *not* mutually exclusive, so the requirement is improper. The Examiner objects to these claims based on the alleged search burden involved. MPEP 806.04(f), however, explicitly states that "***to require restriction between claims limited to species, the claims must not overlap in scope***" (emphasis added, extraneous punctuation removed). The presence or absence of a search burden is irrelevant to the requirement for restriction, which is improper on its face.

Thus, as noted above, Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43 and 46 are presented for examination.

Rejection Under 35 U.S.C. §102 on the Basis of OGLE

The Examiner has rejected Claims 1, 5, 10-11, 17-19, 23, 26, 31-32, 39-43 and 46 under 35 U.S.C. §102(b) on the basis of Ogle et al (U.S. Patent Number 6,491,617) ("OGLE"). This rejection is respectfully traversed.

For a reference to anticipate a claim it must disclose each and every element of the claim. *See* MPEP 2131 and cases cited therein, especially *Richardson v. Suzuki Motor Co.*, 868 F.2d

1226, 1236; 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304; 198 U.S.P.Q. 344, 346 (Fed. Cir. 1978).

In the previous Amendment to Claim 1 it was noted that the rejection under §102(b) was believed to be moot because amended Claim 1 requires microparticles, at least a portion of which are attached to the surface of the adhesive region, wherein the therapeutic agent is neither partially nor fully embedded within the microparticles. These features are neither taught nor suggested by OGLE. The Examiner has not addressed these issues in the current Office Action.

First, OGLE does not use an adhesive region comprising an adhesive. OGLE uses binding interactions of the exogenous storage structures to the biocompatible material such as covalent binding interactions to target specific structures within the material (see col.12, lines 25-57). Some of these interactions to tissues require specific pH conditions.

The Examiner's discussion of possible dipping or spraying techniques mentioned by OGLE does not include any mention of how to keep the particles on the surface absent the bonding techniques described elsewhere in OGLE. In fact, OGLE states that for the dipping and spraying techniques:

> *the medical device can be stored appropriately to maintain the particles appropriately on the surface of the medical device.*(col. 16, lines 50-51).

Thus, OGLE recognizes the problems associated with these techniques, problems which the current invention overcomes.

Second, OGLE does not use a therapeutic agent adhered to the surface of an adhesive region, particularly where the therapeutic agent is neither partially nor fully embedded within microparticles.

Third, OGLE does not use microparticles attached to a surface of an adhesive region, particularly where a therapeutic agent is neither partially nor fully embedded within the microparticles.

Since OGLE does not teach each and every element of the invention, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) is therefore respectfully requested.

Rejection Under 35 U.S.C. §103 Based on OGLE

The Examiner has rejected Claims 1, 5, 10-11, 17-19, 23, 26, 31-32, 40, 43 and 46 under 35 U.S.C. §103(a) as being unpatentable over OGLE. This rejection is respectfully traversed.

It is respectfully submitted that the Examiner has not met his burden of establishing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings of the various references. Second, there must be a reasonable expectation of success. Third and finally, the prior art reference (or references when combined) must teach or suggest all the claimed features. In addition, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure. *In re Vaeck*, 947 F.2d 488; 201 U.S.P.Q. 1438 (Fed. Cir. 1991).

For this rejection, the Examiner has chosen to rely on OGLE alone. As noted above, the features of the present invention are neither taught nor suggested by OGLE.

First, OGLE does not use an adhesive region comprising an adhesive. OGLE uses binding interactions of the exogenous storage structures to the biocompatible material such as covalent binding interactions to target specific structures within the material (see col.12, lines 25-57). Some of these interactions to tissues require specific pH conditions. The Examiner's discussion of possible dipping or spraying techniques mentioned by OGLE does not include any mention of how to keep the particles on the surface absent the bonding techniques described elsewhere in OGLE. In fact, OGLE states that for the dipping and spraying techniques:

> *the medical device can be stored appropriately to maintain the particles appropriately on the surface of the medical device.*(col. 16, lines 50-51)

Thus, OGLE recognizes the problems associated with these techniques, problems which the current invention overcomes.

Second, OGLE does not use a therapeutic agent adhered to the surface of an adhesive region, particularly where the therapeutic agent is neither partially nor fully embedded within microparticles.

Third, OGLE does not use microparticles attached to a surface of an adhesive region particularly where a therapeutic agent is neither partially nor fully embedded within the microparticles.

Also, as noted by the Examiner, OGLE is silent regarding:

(a) the therapeutic agent being embedded or not within the microparticles; and

(b) the size of the microscopic molecules.

Given the importance of releasing the therapeutic agent at an appropriate time and in an appropriate place, the Examiner's assertions of what choices would or could be made is not supported or sufficient. The Examiner is merely inviting experimentation. As noted in the MPEP in Section 2143.01 [emphasis added]:

*A statement that modifications of the prior art to meet the claimed invention would have been "'well within the ordinary skill of the art at the time the claimed invention was made'" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). **'''>[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" KSR, 550 U.S. at ___, 82 USPQ2d at 1396 quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).*

Since OGLE does not teach or suggest each and every element of the invention and the Examiner is relying solely on OGLE for this rejection, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(b) is therefore respectfully requested.

In response to the case law discussed by the Examiner, the following must be noted:

With regard to *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966), cited by the Examiner, this case is not on point, as this is legal precedent pertaining to a change in ***shape***. See MPEP 2144.04.II.B.

With regard to *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965), cited by the Examiner, this case involved making one component integral with another component, which is irrelevant to the facts at hand. See MPEP 2144.04.V.B.

With regard to the Examiner's statement that "[t]his recitation does not impart patentability to the claims absent a showing of superior and unexpected results," it is of course well known that unexpected results can be used to overcome a *prima facie* case of obviousness. See, e.g., MPEP 716.02(a)-(g). Here, however, a *prima facie* case has not been made out, so unexpected results are not of any relevance.

Rejection Under 35 U.S.C. §103 Based on OGLE in View of PINCHUK

The Examiner has rejected Claims 39 and 42 under 35 U.S.C. §103(a) as being unpatentable over OGLE in view of Pinchuk et al (U.S. Patent No. 6,545,097) ("PINCHUK"). This rejection is respectfully traversed.

This rejection is traversed for the reasons previously described for OGLE. The Examiner cites PINCHUK for its teaching of an implantable device with a biocompatible degradable polymer comprising a therapeutic agent and covered with a sheath to prevent premature therapeutic agent release.

The citation to PINCHUK does not appear to be relevant to the present invention.

First, PINCHUK's discussion of a sheath, which is a separate structure, is not relevant to Claims 39 and 42 which uses the term "layer". PINCHUK makes this distinction when it describes therapeutic-agent-loaded copolymers which can be a copolymer as a coating on the device or a component of the device (see col. 14, lines 9-11) in contrast to a sheath which is used only temporarily during insertion of the stent or catheter into the body to prevent premature therapeutic agent release (see col. 14, lines 23-26). The sheath is normally then retracted after insertion and PINCHUK does not provide otherwise.

In contrast to PINCHUK, the present invention provides at paragraph 51:

> *In some embodiments of the invention, an implantable or insertable medical device is further provided with an optional biodisintegrable protection layer to prevent premature loss of the therapeutic agent. The biodisintegrable protection layer covers and protects the therapeutic-containing regions of the device during deployment, but disintegrates (e.g., dissolves or is enzymatically or hydrolytically degraded) after being situated at a location within a patient, thereby allowing the therapeutic agent to be released.*

This optional feature of the present invention provides for the disintegration of a layer that is integral to the device, not a separate physical structure that is mechanically removed. This point is also supported by the description of the term "layer", in paragraph 25 of the current specification which defines the term as follows:

> *As used herein a "layer" of a given material is a region of that material whose thickness is small compared to both its length and width. As used herein, a layer need not be planar, for example, taking on the contours of an underlying substrate. Layers can be discontinuous (e.g., patterned). Terms such as "film," "layer" and "coating" may be used interchangeably herein.*

Thus, as used in the current invention, a sheath would not be included in the definition of "layer".

Second, the invention of OGLE comprises technology that is not combinable with PINCHUK. OGLE does not even mention the optional use of any additional coating on its devices. The technology of OGLE is based on the storage and release of the described agents by direct application of the medical device against the adjacent wall (OGLE, Abstract). This description in OGLE may be viewed as teaching away from the use of any additional layer, much less the sheath of PINCHUK. Any assertion by the Examiner that a layer could be used with OGLE is only unsupported speculation.

Since OGLE in view of PINCHUK does not teach or suggest each and every element of the invention, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(b) is therefore respectfully requested.

CONCLUSION

Applicants submit that Claims 1-5, 10-13, 15, 17-21 and 23-46 are in condition for allowance. Reconsideration is requested and an early Notice of Allowance is requested.

Should the Examiner be of the view that an interview would expedite consideration of this Response or of the application at large, the Examiner is requested to telephone the Applicant's attorney at the number listed below in order to resolve any outstanding issues in this case.

Respectfully submitted,

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